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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,682	WHEELER ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☒ Claim(s) *1, 8, 13, 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because "upstream" is misspelled in line 6.

Claim 8 is objected to because the recitation "the probe are" lacks subject verb agreement.

Claim 13 is objected to because "upstream" is misspelled in line 4.

Claim 20 is objected to because the recitation "the probe are" lacks subject verb agreement.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 are indefinite in Claim 1 because the claim is drawn to a method of designing a probe array, but the claims do not recited method steps for array design. Therefore, it is unclear whether the method step achieve the claimed method.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-24 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Chaganti et al (U.S. Patent No. 6,309,860, issued 30 October 2001).

Regarding Claim 1, Chaganti et al disclose a method of designing nucleic acid probes to a transcription cluster (i.e. BLC-8 transcripts) comprising selecting a first set of probes comprising at least one probe (i.e. probes A & C) targeting a first region immediately upstream of a first polyadenylation site in a transcription center and selecting a second probe comprising at least one probe (i.e. multiple copies of probe B) targeting a second region immediately upstream of a second polyadenylation site wherein the first and second regions are different (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 2, Chaganti et al disclose the method wherein the polyadenylation sites are alternative polyadenylation sites (Column 12, lines 32-35).

Regarding Claim 3, Chaganti et al disclose the method wherein the first polyadenylation site is a putative polyadenylation site (Column 12, lines 32-35).

Regarding Claim 4, Chaganti et al disclose the method wherein the first region is within 800 bases upstream of the first polyadenylation site and the second region is within 800 bases upstream of the second polyadenylation site (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 5, Chaganti et al disclose the method wherein the first region is within 600 bases upstream of the first polyadenylation site and the second region is within 600 bases upstream of the second polyadenylation site (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 6, Chaganti et al disclose the method wherein the target nucleic acid represents a cluster of transcript sequences including RNA and ESTs i.e. both types of bcl-8 transcripts (Column 12, lines 32-35).

Regarding Claim 7, Chaganti et al disclose the method wherein the first polyadenylation site is a full length mRNA and the first set of probes (i.e. A & C) are selected to target the full length mRNA as an exemplar sequence of the cluster (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 8, Chaganti et al disclose the method wherein the first polyadenylation site is shared by a stack of sequences in the cluster (i.e. sequences expressed in different tissues) and the probes are selected to target the consensus sequence of the cluster and wherein the stack of sequences comprises at least two sequences i.e. when the internal polyadenylation site is the named the "first polyadenylation site", the first probe set comprises A & B. Probe set A & B target the consensus sequences comprising at least two sequences (Fig. 6).

Regarding Claims 9-10, Chaganti et al disclose the method wherein the stack of sequences comprises at least 8 sequences i.e. at least 8 different tissues (Fig. 6).

Regarding Claims 11-12, Chaganti et al disclose the method wherein the probe sets comprise at least 10 probes i.e. multiple copies of probes A & B or A & C (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 13, Chaganti et al disclose an array of nucleic acid probes comprising at least one probe (i.e. probes A & C) targeting a first region immediately upstream of a first polyadenylation site in a transcription center (i.e. BCL-8) and at least one second probe (i.e. multiple copies of probe B) targeting a second region immediately upstream of a second polyadenylation site wherein the first and second regions are different (Column 12, lines 32-51 and Fig. 6). It is noted that the claims are drawn to a nucleic acid probe array. However, the claims are not limited to immobilized or addressable probes. The claims are given the broadest reasonable interpretation consistent with the broad claim language. As such, the broadly claimed probes encompass the probes of Chaganti et al.

Regarding Claim 14, Chaganti et al disclose the probes wherein the polyadenylation sites are alternative polyadenylation sites (Column 12, lines 32-35).

Regarding Claim 15, Chaganti et al disclose the probes wherein the first polyadenylation site is a putative polyadenylation site (Column 12, lines 32-35).

Regarding Claim 16, Chaganti et al disclose the probes wherein the first region is within 800 bases upstream of the first polyadenylation site and the second region is within 800 bases upstream of the second polyadenylation site (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 17, Chaganti et al disclose the probes wherein the first region is within 600 bases upstream of the first polyadenylation site and the second region is within 600 bases upstream of the second polyadenylation site (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 18, Chaganti et al disclose the probes wherein the target nucleic acid represents a cluster of transcript sequences including RNA and ESTs i.e. both types of bcl-8 transcripts (Column 12, lines 32-35).

Regarding Claim 19, Chaganti et al disclose the probes wherein the first polyadenylation site is a full length mRNA and the first set of probes (i.e. A & C) are selected to target the full length mRNA as an exemplar sequence of the cluster (Column 12, lines 32-51 and Fig. 6).

Regarding Claim 20, Chaganti et al disclose the probes wherein the first polyadenylation site is shared by a stack of sequences in the cluster (i.e. sequences expressed in different tissues) and the probes are selected to target the consensus sequence of the cluster and wherein the stack of sequences comprises at least two sequences i.e. when the internal polyadenylation site is the named the "first polyadenylation site", the first probe set comprises A & B. Probe set A & B target the consensus sequences comprising at least two sequences (Fig. 6).

Regarding Claims 21-22, Chaganti et al disclose the probes wherein the stack of sequences comprises at least 8 sequences i.e. at least 8 different tissues (Fig. 6).

Regarding Claims 22-23, Chaganti et al disclose the probes wherein the probe sets comprise at least 10 probes i.e. multiple copies of probes A & B or A & C (Column 12, lines 32-51 and Fig. 6).

6. Claims 1-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al (U.S. Patent No. 5,643,783, issued 1 July 1997).

Regarding Claim 1, Olsen et al disclose a method of designing nucleic acid probes to a transcription cluster (i.e. collagen transcripts) comprising selecting a first set of probes comprising at least one probe (i.e. probe A) targeting a first region immediately upstream of a first polyadenylation site in a transcription center and selecting a second probe comprising at least one probe (i.e. probe B) targeting a second region immediately upstream of a second polyadenylation site wherein the first and second regions are different (Column 9, lines 45-59 and Fig. 5).

Regarding Claim 2, Olsen et al disclose the method wherein the polyadenylation sites are alternative polyadenylation sites (Column 4, line 60-Column 5, line 2).

Regarding Claim 3, Olsen et al disclose the method wherein the first polyadenylation site is a putative polyadenylation site (Column 4, line 60-Column 5, line 2).

Regarding Claim 4, Olsen et al disclose the method wherein the first region is within 800 bases upstream of the first polyadenylation site and the second region is within 800 bases upstream of the second polyadenylation site (Fig. 5 and Column 11, lines 10-32).

Regarding Claim 5, Olsen et al disclose the method wherein the first region is within 600 bases upstream of the first polyadenylation site and the second region is within 600 bases upstream of the second polyadenylation site (Column 11, lines 10-32 and Fig. 5).

Regarding Claim 6, Olsen et al disclose the method wherein the target nucleic acid represents a cluster of transcript sequences including RNA and ESTs i.e. collagen transcripts (Column 11, lines 10-32).

Regarding Claim 7, Olsen et al disclose the method wherein the first polyadenylation site is a full length mRNA and the first set of probes (i.e. A) are selected to target the full length mRNA as an exemplar sequence of the cluster (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claim 8, Olsen et al disclose the method wherein the first polyadenylation site is shared by a stack of sequences in the cluster (i.e. sequences expressed in different tissues) and the probes are selected to target the consensus sequence of the cluster and wherein the stack of sequences comprises at least two sequences i.e. different transcripts (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claims 9-10, Olsen et al disclose the method wherein the stack of sequences comprises at least 8 sequences i.e. at least 8 different tissues (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claims 11-12, Olsen et al disclose the method wherein the probe sets comprise at least 10 probes i.e. multiple copies of probes A & B (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claim 13, Olsen et al disclose an array of nucleic acid probes comprising at least one probe (i.e. probe A) targeting a first region immediately upstream of a first polyadenylation site in a transcription center (i.e. collagen transcripts) and selecting a second probe comprising at least one probe (i.e. probe B) targeting a second region immediately upstream of a second polyadenylation site wherein the first and second regions are different (Column 9, lines 45-59 and Fig. 5). It is noted that the claims are drawn to a nucleic acid probe array. However, the claims are not limited to immobilized or addressable probes. The claims are given the broadest reasonable interpretation consistent with the broad claim language. As such, the broadly claimed probes encompass the probes of Olsen et al.

Regarding Claim 14, Olsen et al disclose the method wherein the polyadenylation sites are alternative polyadenylation sites (Column 4, line 60-Column 5, line 2).

Regarding Claim 15, Olsen et al disclose the method wherein the first polyadenylation site is a putative polyadenylation site (Column 4, line 60-Column 5, line 2).

Regarding Claim 16, Olsen et al disclose the method wherein the first region is within 800 bases upstream of the first polyadenylation site and the second region is within 800 bases upstream of the second polyadenylation site (Fig. 5 and Column 11, lines 10-32).

Regarding Claim 17, Olsen et al disclose the method wherein the first region is within 600 bases upstream of the first polyadenylation site and the second region is within 600 bases upstream of the second polyadenylation site (Column 11, lines 10-32 and Fig. 5).

Regarding Claim 18, Olsen et al disclose the method wherein the target nucleic acid represents a cluster of transcript sequences including RNA and ESTs i.e. collagen transcripts (Column 11, lines 10-32).

Regarding Claim 19, Olsen et al disclose the method wherein the first polyadenylation site is a full length mRNA and the first set of probes (i.e. A) are selected to target the full length mRNA as an exemplar sequence of the cluster (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claim 20, Olsen et al disclose the method wherein the first polyadenylation site is shared by a stack of sequences in the cluster (i.e. sequences expressed in different tissues) and the probes are selected to target the consensus sequence of the cluster and wherein the stack of sequences comprises at least two sequences i.e. different transcripts (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claims 21-22, Olsen et al disclose the method wherein the stack of sequences comprises at least 8 sequences i.e. at least 8 different tissues (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

Regarding Claims 23-24, Olsen et al disclose the method wherein the probe sets comprise at least 10 probes i.e. multiple copies of probes A & B (Column 9, lines 45-59; Column 11, lines 10-32 and Fig. 5).

7. Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie et al (U.S. Patent No. 6,268,147, filed 2 November 1999).

Regarding Claim 1, Beattie et al disclose a method of designing a probe array to target a transcription cluster comprising selection a first probe comprising at least one probe targeting a first region immediately upstream of a first polyadenylation site in a transcription center and selecting a second probe comprising at least one probe targeting a second region immediately

upstream of a second polyadenylation site wherein the first and second regions are different i.e. probes of Beattie target regions adjacent to the poly-A tail of mRNA and comprise poly-T sequence plus 1-4 bases comprising a mixture of all 4 bases whereby each different probe will target a different polyadenylation site because the bases adjacent to the poly-T sequence of the probe will recognize different sequences (Column 14, line 59-Column 15, line 15 and Example 14, Column 34, lines 1-58).

Regarding Claim 2, Beattie et al disclose the method wherein the polyadenylation sites are alternative polyadenylation sites (Example 14, Column 34, lines 1-58).

Regarding Claim 3, Beattie et al disclose the method wherein the first polyadenylation site is a putative polyadenylation site (Example 14, Column 34, lines 1-58).

Regarding Claim 4, Beattie et al disclose the method wherein the first region is within 800 bases upstream of the first polyadenylation site and the second region is within 800 bases upstream of the second polyadenylation site i.e. adjacent to the poly-A tail (Example 14, Column 34, lines 1-58).

Regarding Claim 5, Beattie et al disclose the method wherein the first region is within 600 bases upstream of the first polyadenylation site and the second region is within 600 bases upstream of the second polyadenylation site i.e. adjacent to the poly-A tail(Example 14, Column 34, lines 1-58).

Regarding Claim 6, Beattie et al disclose the method wherein the target nucleic acid represents a cluster of transcript sequences including RNA and ESTs (Example 14, Column 34, lines 1-58).

Regarding Claim 7, Beattie et al disclose the method wherein the first polyadenylation site is a full length mRNA and the first set of probes are selected to target the full length mRNA as an exemplar sequence of the cluster (Column 14, line 59-Column 15, line 15; Example 14, Column 34, lines 1-58; and Column 36, lines 25-30).

Regarding Claim 8, Beattie et al disclose the method wherein the first polyadenylation site is shared by a stack of sequences in the cluster and the probes are selected to target the consensus sequence of the cluster and wherein the stack of sequences comprises at least two sequences cluster (Column 14, line 59-Column 15, line 15; Example 14, Column 34, lines 1-58.

Regarding Claims 9-10, Beattie et al disclose the method wherein the stack of sequences comprises at least 8 sequences i.e. mixture of all 4 bases (Example 14, Column 34, lines 1-58).

Regarding Claims 11-12, Beattie et al disclose the method wherein the probe sets comprise at least 10 probes i.e. mixture of all 4 bases (Example 14, Column 34, lines 1-58 and Fig. 1).

Regarding Claim 13, Beattie et al disclose an array of nucleic acid probes comprising at least one probe targeting a first region immediately upstream of a first polyadenylation site in a transcription center and selecting a second probe comprising at least one probe targeting a second region immediately upstream of a second polyadenylation site wherein the first and second regions are different i.e. probes of Beattie target regions adjacent to the poly-A tail of mRNA and comprise poly-T sequence plus 1-4 bases comprising a mixture of all 4 bases whereby each different probe will target a different polyadenylation site because the bases adjacent to the poly-T sequence of the probe will recognize different sequences (Example 14, Column 34, lines 1-58).

Regarding Claim 14, Beattie et al disclose the array wherein the polyadenylation sites are alternative polyadenylation sites (Example 14, Column 34, lines 1-58).

Regarding Claim 15, Beattie et al disclose the array wherein the first polyadenylation site is a putative polyadenylation site (Example 14, Column 34, lines 1-58).

Regarding Claim 16, Beattie et al disclose the array wherein the first region is within 800 bases upstream of the first polyadenylation site and the second region is within 800 bases

upstream of the second polyadenylation site i.e. adjacent to the poly-A tail (Example 14, Column 34, lines 1-58).

Regarding Claim 17, Beattie et al disclose the array wherein the first region is within 600 bases upstream of the first polyadenylation site and the second region is within 600 bases upstream of the second polyadenylation site i.e. adjacent to the poly-A tail(Example 14, Column 34, lines 1-58).

Regarding Claim 18, Beattie et al disclose the array wherein the target nucleic acid represents a cluster of transcript sequences including RNA and ESTs (Example 14, Column 34, lines 1-58).

Regarding Claim 19, Beattie et al disclose the array wherein the first polyadenylation site is a full length mRNA and the first set of probes are selected to target the full length mRNA as an exemplar sequence of the cluster (Column 14, line 59-Column 15, line 15; Example 14, Column 34, lines 1-58; and Column 36, lines 25-30).

Regarding Claim 20, Beattie et al disclose the array wherein the first polyadenylation site is shared by a stack of sequences in the cluster and the probes are selected to target the consensus sequence of the cluster and wherein the stack of sequences comprises at least two sequences cluster (Column 14, line 59-Column 15, line 15; Example 14, Column 34, lines 1-58.

Regarding Claims 21-22, Beattie et al disclose the array wherein the stack of sequences comprises at least 8 sequences i.e. mixture of all 4 bases (Example 14, Column 34, lines 1-58).

Regarding Claims 23-24, Beattie et al disclose the array wherein the probe sets comprise at least 10 probes i.e. mixture of all 4 bases (Example 14, Column 34, lines 1-58 and Fig. 1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie et al (U.S. Patent No. 6,268,147, filed 2 November 1999) in view of Lockhart et al (U.S. Patent No. 5,556,752, filed 24 October 1994).

Regarding Claims 25-26, Beattie et al teaches the array of nucleic acid probes comprising at least one probe targeting a first region immediately upstream of a first polyadenylation site in a transcription center and selecting a second probe comprising at least one probe targeting a second region immediately upstream of a second polyadenylation site wherein the first and second regions are different (Example 14, Column 34, lines 1-58) but they are silent regarding the probe density. However, probe density of greater than 400 different probes/cm^2 (Claim 25) and greater than 1000 different probes/cm^2 (Claim 26) were well known in the art at the time the claimed invention was made as taught by Lockhart et al who specifically teach polyadenylation site-specific probes immobilized at a density greater than 1000 different probes/cm^2 (Column 10, lines 45-55 and Column 13, lines 19-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe density of Lockhart et al to the probe array of Beattie to thereby analyze the genomes of complete organisms on a single support as desired by Beattie (Column 34, lines 50-58).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 11, 2003